
International Cooperation on Harmonisation of Technical Requirements
for Registration of Veterinary Medicinal Products
VICH
Vaccine Deployment in the Field: The Uganda Experience
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Uganda National Drug Authority

Scope of the presentation

- Introduction
- Marketing Authorisation(MA)
- Post Registration Activities
- VICH Guidelines in use
- Way Forward

Introduction(Cont.)

Map of Africa showing the location of Uganda

Introduction(Cont.)

Uganda's Livestock Population

Species	Number (millions)
Cattle	14.2
Goats	16.0
Sheep	4.4
Pigs	4.1
Poultry	47.6

Source: UBOS, MAAIF(2017)

Introduction(Cont.)

- National Drug Authority(NDA) regulates veterinary medicinal products in addition to human medicines
- The NDP Act governs the operations, a number of statutory instruments are also in force including The National Drug Policy And Authority(Registration) Regulations, 2014 No 29 that provides:

  - All products shall be registered in Uganda before sale or distribution.

  - A person who intends to manufacture, import or export a product shall, prior to the manufacture, importation or exportation of the product, apply to the Authority for registration of the product(Marketing Authorisation).

- Other regulatory functions carried out include regulation of Clinical Trials, Vigilance, Inspection of Premises and GMP Market Surveillance and Control and Laboratory Testing.

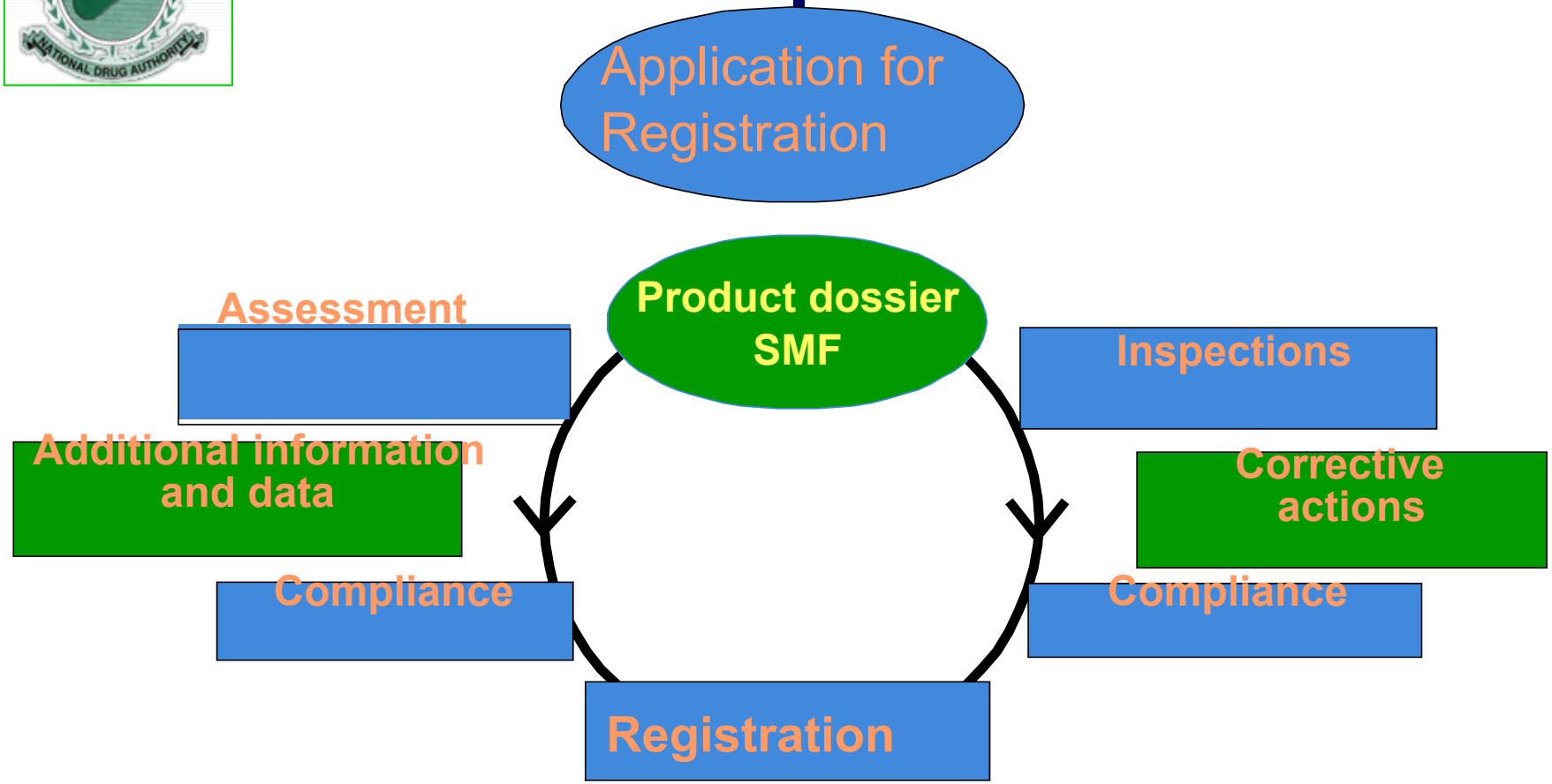
Marketing Authorisation

- National Procedure
- East African Community Harmonised Procedure
- Authorisation of vaccines use in special circumstances(Section 8/4 of the NDP Act)

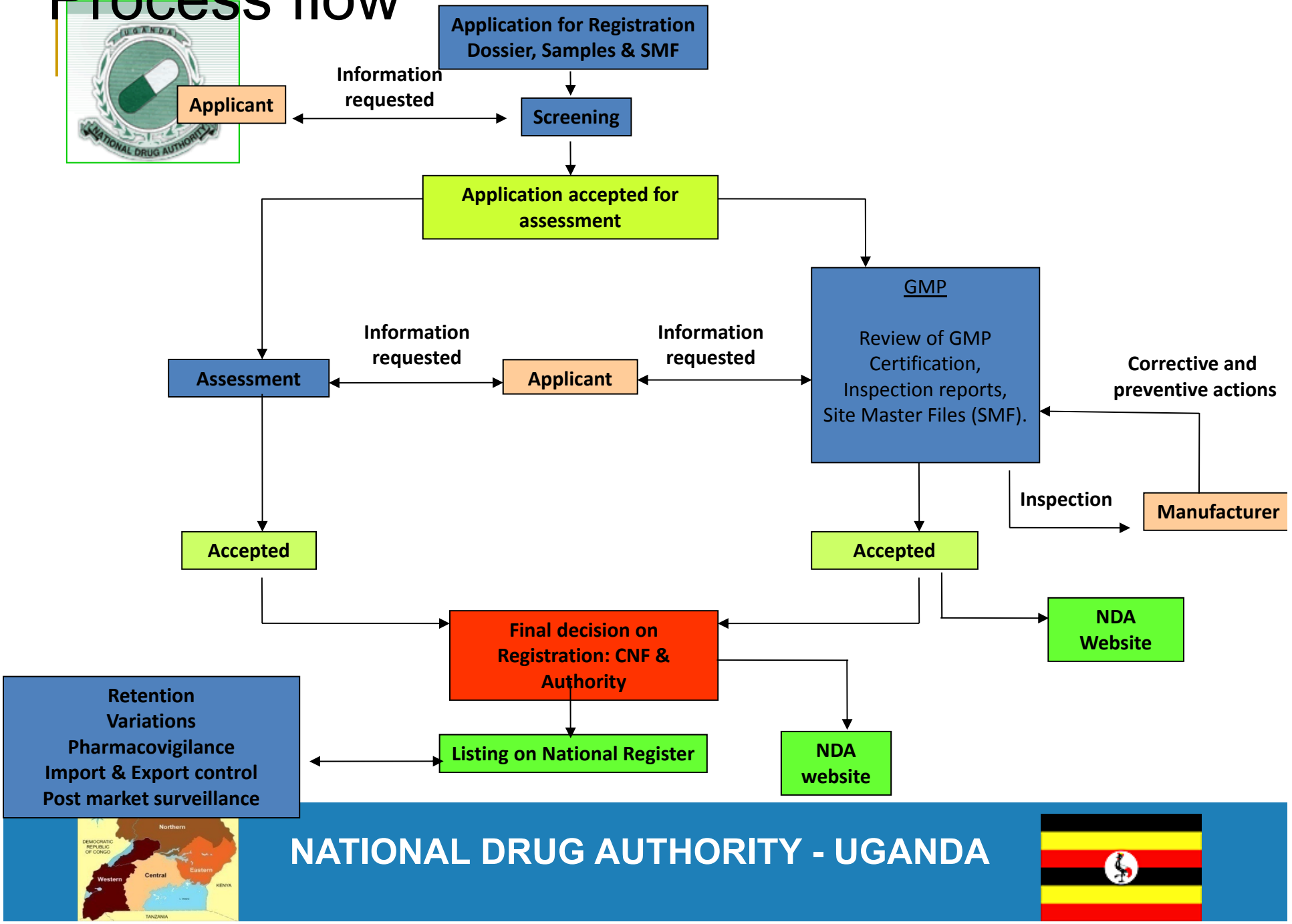
MA: National Procedure

- ✓ All applications received at the National level; the process service delivery timeline is 120 days for vaccines, overwhelming majority of applications are handled through the National Procedure. The details of the procedure are provided below

Steps in REGISTRATION



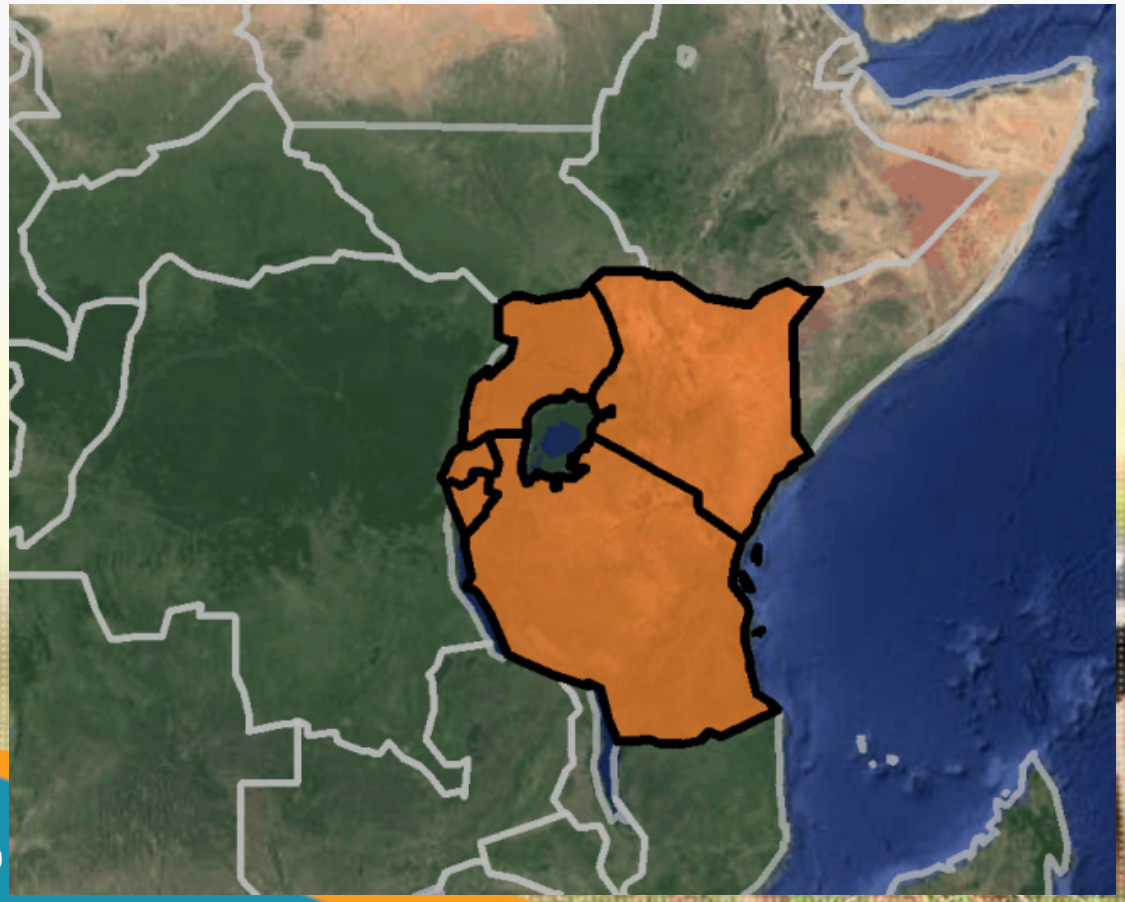
Process flow

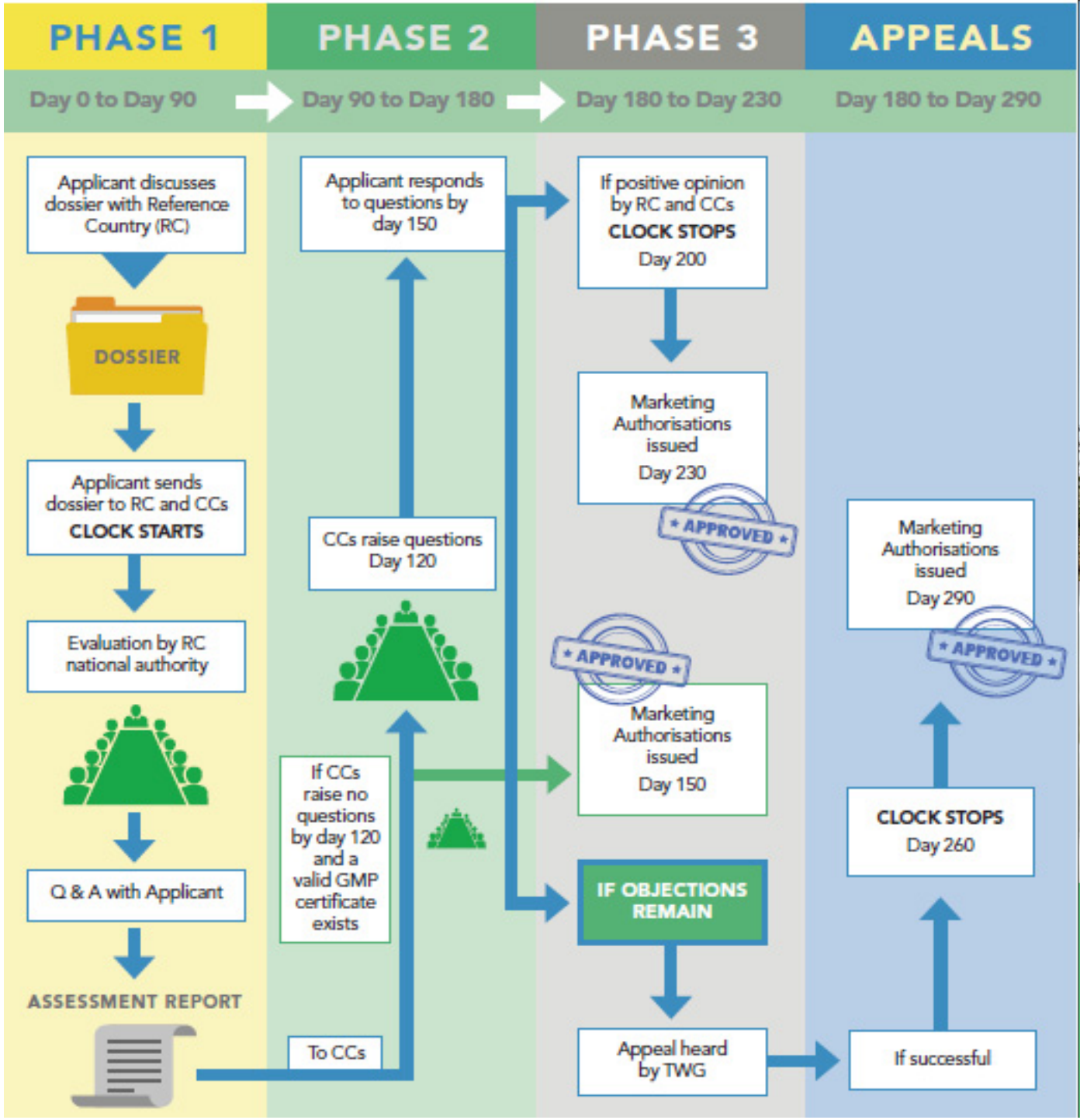


NATIONAL DRUG AUTHORITY - UGANDA

MA: EAC Harmonisation Procedure

- Mutual Recognition Procedure in the EAC(Burundi, Kenya, Rwanda, Tanzania, Uganda and lately South Sudan). Started in 2017 following the drafting of common technical registration requirements




PHASE 1
PHASE 2
PHASE 3
APPEALS
Day 0 to Day 90
Day 90 to Day 180
Day 180 to Day 230
Day 180 to Day 290
Applicant discusses dossier with Reference Country (RC)
DOSSIER
Applicant sends dossier to RC and CCs
CLOCK STARTS
Evaluation by RC national authority
Q & A with Applicant
ASSESSMENT REPORT
To CCs
If CCs raise no questions by day 120 and a valid GMP certificate exists
CCs raise questions Day 120
Applicant responds to questions by day 150
If positive opinion by RC and CCs
CLOCK STOPS
Day 200
Marketing Authorisations issued
Day 230
* APPROVED *
* APPROVED *
Marketing Authorisations issued
Day 150
IF OBJECTIONS REMAIN
Appeal heard by TWG
If successful
Marketing Authorisations issued
Day 290
* APPROVED *
CLOCK STOPS
Day 260


Working together to uniformly license veterinary medicines in East Africa:
How the East African Community's Mutual Recognition Procedure works
1st edition
East African Community, August 2016
FAQs
Mutual Recognition Procedure for the registration of veterinary medicines in the East African Community

Post Registration Activities

- Inspection of Premises
- Import Control
- Vigilance
- Market Surveillance and Control
- Laboratory Testing

VICH Guidelines in Use

> Guidelines for MA of Veterinary Pharmaceutical Products :

VICH GL 18, 10, 39, 1, 2, 5, 3, 34, 31, 37, 23, 28, 27, 332, 33, 36, 6, 38 and 43

> Guidelines for MA of Immunological Veterinary Products:

VICH GL: 26, 17,44,41

> Draft Veterinary Pharmacovigilance Guidelines:

VICH GL 24

Way Forward

- The use of VICH GL has greatly enhanced the MA of vaccines in Uganda
- The GL however are mainly in pre registration activities
- Focus on post registration activities in order to enhance combating the presence on the market of substandard and Falsified Products
- VICH is encouraged to also draft guidelines for these activities in order to protect and promote Animal Health.

Acknowledgements

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